REMARKS

Claims 111-170 are pending in the present application. Reconsideration and allowance of the present application in view following remarks are respectfully requested.

I. INFORMATION DISCLOSURE STATEMENT

The Examiner states that the Information Disclosure Statement ("IDS") submitted on March 10, 2006 is in compliance with the provisions of 37 C.F.R. § 1.97. However, the Examiner requests that Applicants point out any particular references cited in the IDS that they are aware of that are directly relevant to the claimed invention. In response, Applicants submit that in the IDS, Applicants have brought to the Examiner's attention references that relate to a litigation and proceedings concerning related U.S., European, and German patents. Applicants are not aware of any particular references that are believed to be directly relevant to the claimed invention.

II. THE CLAIM REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, ("WRITTEN DESCRIPTION") SHOULD BE WITHDRAWN

Claims 111-117 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that there is only support in the specification for "substantially free of an elutable material" but no support in the specification as filed for the limitation wherein the topcoat is "free of an elutable material when applied to the undercoat." For the following reasons, Applicants respectfully disagree.

1. The Legal Standard

The test for sufficiency of written description is whether the disclosure of the application "reasonably conveys to the artisan that the inventor had possession" of the claimed subject matter. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983); *accord Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d. 1111, 1117 (Fed. Cir. 1991); *see also, Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985). The criteria for determining sufficiency of written description is set forth in the Guidelines for Examination of Patent Applications

Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement (the "Guidelines") (published in Volume 66, Number 4, pages 1099-1111 of the Federal Register on January 5, 2001), which specifies that:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see (1)(a), above), reduction to drawings (see (1)(b), above), or [i] by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, [ii] by functional characteristics coupled with a known or disclosed correlation between function and structure, or [iii] by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see (1)(c), above). *Id.* at page 1106, column 3, lines 13-29.

Where the specification discloses any relevant, identifying characteristics, *i.e.*, physical, chemical and/or functional characteristics sufficient to allow a skilled artisan to recognize that applicant was in possession of the claimed invention, a rejection for lack of written description under 35 U.S.C. § 112, first paragraph, is misplaced. *Id.*

2. <u>The Pending Claims Comply With The Written Description Requirement</u>

Claims 111-117 as well as the other pending claims 118-170 are directed to stents having a portion thereof covered with a coating comprising a topcoat and an undercoat, wherein the topcoat is free of an elutable material when applied to the undercoat. For the following reasons, Applicants submit that the specification clearly describes the subject matter of the pending claims in such a way as to reasonably convey to one skilled in the relevant art that Applicants, at the time the application was filed, had possession of the claimed invention.

Applicants respectfully direct the Examiner's attention to Example 1 on pages 20-21 of the specification. This example, along with corresponding Figure 8, describe the making and using of stents covered with coatings comprising a flurosilicone topcoat and a dexamethasone undercoat. In particular, the specification describes a first stent having a flurosilicone topcoat containing heparin and a second stent having a flurosilicone-only topcoat (*i.e.*, free of heparin) (see page 21, lines 6-14). Contrary to the Examiner's contention, the specification adequately describes a stent with a topcoat which is free of an elutable material when applied to the undercoat (*i.e.* the second stent in the example). Thus, Applicants respectfully submit that the rejection is in error and should be withdrawn.

III. THE CLAIM REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, ("ENABLEMENT") SHOULD BE WITHDRAWN

Claims 111-170 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner alleges that while the specification discloses the use of "substantially pure polymeric material," to form topcoats "substantially free of an elutable material" the specification fails to enable one of ordinary skill to make the coating "free of an elutable material when applied to the undercoat." For the following reasons, Applicants respectfully disagree.

1. The Legal Standard

The enablement requirement refers to the requirement of 35 U.S.C. § 112, first paragraph, that the specification describes (1) how to make and (2) how to use the invention. *See* MPEP § 2164. The test for enablement is whether one reasonably skilled in the art could make and use the invention, without undue experimentation, from the disclosure in the patent specification coupled with information known in the art at the time the patent application was filed. *United States v. Telectronics Inc.*, 857 F.2d 778, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988). Enablement is not precluded even if some experimentation is necessary. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int'l Trade Comm'n 1983).

By definition, undue experimentation is experimentation that would require a level of ingenuity beyond what is expected from one of ordinary skill in the field. *Fields v. Conover,* 443 F.2d 1386, 1392, 170 U.S.P.Q. 276, 279 (C.C.P.A. 1971). The factors that are relevant in determining what constitutes undue experimentation as set forth by the Federal Circuit (citing *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (Bd. Pat. App. & Int. 1986)) include: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." Any conclusion of non-enablement must be based on the evidence as a whole, and not based on an analysis of only one of the factors while ignoring one or more of the others. *In re Wands*, 858 F.2d 731, 740, 8 U.S.P.Q.2d 1400, 1406 (Fed. Cir. 1988).

The Patent Office must establish a *prima facie* case of non-enablement in order to properly reject a claim on that basis. "When rejecting a claim under the enablement requirement of § 112, the Patent Office bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention in the specification of the application..." *In re Wright*, 999 F.2d 1557, 1561, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). The Patent Office's *prima facie* case should address each of the *Wands* factors since "[i]t is improper to conclude that a disclosure is not enabling based on an analysis of only one of the [*Wands*] factors while ignoring one or more of the others." *See* MPEP § 2164.01(a), citing *Wands*, 8 U.S.P.Q.2d at 1407. Where the Patent Office does not provide evidence regarding one or more *Wands* factors, applicant presumes that such factors support the conclusion that the claims at issue are fully enabled.

2. The Pending Claims Comply With The Enablement Requirement

Applicants submit that one skilled in the art, based on the disclosure in the patent specification coupled with information known in the art at the time the patent application was filed, can make and use, without undue experimentation, a stent covered with a coating comprising a topcoat and an undercoat, wherein the topcoat is free of an elutable material when applied to the undercoat. As previously discussed, the specification describes how to make and use a stent having a topcoat free of an elutable material when applied to the undercoat (see, *e.g.*, page 21, lines 6-14; and Figure 8). Contrary to the Examiner's allegation, the specification enables one of ordinary skill to make a stent having a topcoat free of an elutable material when applied to the undercoat.

In the Office Action, the Examiner did not address any of the Wands factors and failed to establish a *prima facie* case of non-enablement. Applicants submit that when all of the Wands factors are considered, one skilled in the art can determine, without undue experimentation, how to make and use the claimed stent. First, the quantity of experimentation necessary to make a stent with a topcoat that contains no elutable material when applied to an undercoat is routine and not unduly extensive. Second, the amount of direction or guidance presented in the specification for making such a stent is more than sufficient. In fact, the specification provides a working example of making and using such a stent (see, *e.g.*, Example 1). Moreover, the nature of the invention, *i.e.*, coating a stent with a drug-free, pure polymer, is straightforward and not unduly complicated. The relative skill of

those in the art of coating stents is high, and the art of coating stents is predictable. Finally, the breadth of the claims is reasonable and not overly broad. Thus, Applicants submit that the instant specification fully enables one of skill in the art to make and use the invention commensurate in scope with the claims without undue experimentation.

For the foregoing reasons, Applicants respectfully submit that the rejection is in error and should be withdrawn.

CONCLUSION

As all rejections are believed to be overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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